Step-by-Step Instructions for Registering an Institutional Review Board (IRB)

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This form is used by institutions or organizations operating IRBs that review:

1. **Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research; and/or**
2. **Clinical investigations regulated by the Food and Drug Administration (FDA) of HHS**

The IRB Registration form is to be used for the following purposes:

- **To register an IRB if an institution or organization has not previously registered an IRB;**
- **To update or renew the registration of an IRB previously registered by an institution or organization;**
- **To add another IRB to those previously registered by an institution or organization.**

NOTE: Only institutions or organizations that have their own IRB should submit an IRB Registration form. Institutions that do not have their own IRB but rely on the IRB of another institution should not submit an IRB Registration.

ITEM #1 - Has your institution or organization previously registered an IRB with HHS

If yes, go to item #2; if no, go to item #3.

ITEM #2 - What is your institution or organization IORG number?

The IORG number is a unique number assigned by OHRP to your institution or organization the first time your institution or organization registered an IRB. This number should be provided to OHRP whenever your institution or organization subsequently updates or renews the existing registration of any of your IRBs or registers a new IRB. If you do not know your IORG number, search for your institution or organization on the OHRP website at http://ohrp.cit.nih.gov/search/ or contact OHRP using the contact information at http://www.hhs.gov/ohrp/assurances/contact/index.html or by phone at 1-866-447-4777.

ITEM #3 - Name of Institution or Organization Operating the IRB(s)

Provide the full legal name of the institution or organization that is operating the IRB(s) being registered and full mailing address, including country if outside the United States. Also, include the street address if it is different from the mailing address.

ITEM #4 - Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities of the IRB(s)

Provide the full name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of the organization operating the IRB [i.e., the person in your organization who is ultimately responsible for overseeing the activities of the IRB(s)].

ITEM #5 - Contact Person Providing this Registration Information

Provide the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

ITEM #6 - IRB Registration Information (to be completed separately for each IRB being renewed/updated or newly registered)

1. Indicate whether this is a renewal or update of a registration for an IRB already registered with HHS.

   If yes, select Yes and Provide the IRB registration number previously assigned to this IRB by OHRP. OHRP provided that unique number the first time the IRB was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP website at http://ohrp.cit.nih.gov/search/ or contact OHRP using the contact information at http://www.hhs.gov/ohrp/assurances/contact/index.html or by phone at 1-866-447-4777)

   If no, select No, this is a new IRB registration.

2. Provide the IRB Name, if any, that has been assigned by your institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB#1).

   Provide the location of this IRB, including the mailing and street addresses, if different from the mailing and street addresses of the institution or organization, phone number, facsimile number, and electronic mail address

3. For IRBs regulated by OHRP, provide the approximate number of full time equivalent positions devoted to this IRB's administrative activities.

4. For IRBs regulated by OHRP, provide the approximate number of all active protocols. An active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.

5. For IRBs regulated by OHRP, provide the approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.). An active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.

6. For IRBs regulated by FDA provide the following information if this IRB reviews, or intends to review protocols involving products regulated by the Food and Drug Administration (FDA). An active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months.

   1. Provide the approximate number of active protocols involving FDA-regulated products; and

   2. Provide a description of the types of FDA-regulated products involved in FDA protocols (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

7. Provide this IRB chairperson's full name, phone number, and electronic mail address.

   IRB Roster Form

   General Information - Completion of the IRB Roster form is required if your IRB is designated on a Federalwide assurance submitted to OHRP.

If the IRB is designated under an OHRP assurance, be sure your IRB meets the minimum requirements for membership. As detailed at 45 CFR Part 46, an IRB shall:

1. Have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
2. Be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
3. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
4. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
5. Include at least one member who is not otherwise affiliated with the institution operating the IRB and who is not a part of the immediate family of a person who is affiliated with it.
6. Make every nondiscriminating effort to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
7. Have no member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

   An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Instructions - For each listed IRB member:

1. Provide the list of members on your IRB. Primary members should be listed in the top section of the form and alternate members in the lower section. Note: Do not list non-voting individuals who attend IRB meetings. Their attendance may be documented in minutes of the meeting.
2. Provide the "Sex" [e.g., male (M) or female (F)].
3. Provide the highest "Earned Degree(s)" (e.g., Ph.D., M.D., MSW, B.A.).
4. Type "S" if the IRB member is a Scientist or "N" if the IRB member is a Non-scientist.
5. Provide the IRB member's "Primary Scientific or Nonscientific Specialty" (e.g., Sociology, Internal Medicine, Library Services). Also, either in the "Primary Scientific or Nonscientific" field or in "Comments" indicate if a given member provides special representation for the IRB (e.g., prisoner representative, advocate)

6. Type the IRB member's "Affiliation with Institution(s)" (e.g., employees, students, board members, alumni, etc., should be listed as "Y" or "Yes"; members with no affiliation or relationship with the institution operating the IRB other than being an active IRB member should be listed as "N" or "No").

7. Provide any additional relevant information regarding a given IRB member in the "Comments" section (e.g., prisoner representative, advocate).

When listing the alternate members, designate the corresponding number or name of the regular member(s) which a given alternate member represents. This information may be entered in the comments section.

SUBMITTING AN IRB REGISTRATION TO HHS

For IRBs regulated by OHRP: Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless your institution or organization lacks the ability to register its IRB's) electronically.

If your institution or organization lacks the ability to register an IRB electronically, you must send your IRB registration in writing to OHRP. Manually completed IRB may be faxed to (240) 453-8202 or mailed to the following address:

IRB Registration
Division of Policy and Assurances
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

For FDA IRBs: Each IRB may register electronically through http://ohrp.cit.nih.gov/efile. If an IRB lacks the ability to register its IRB(s) electronically, it must send its registration information, in writing, to:

Food and Drug Administration
Office of Good Clinical Practice
Office of Special Medical Programs
10903 New Hampshire Ave., WO32-5103
Silver Spring, MD 20993